



October 29, 2004

Public Information and Records
Integrity Branch (PIRIB) (7502C), Office
of Pesticide Programs (OPP),
Environmental Protection Agency, 1200
Pennsylvania Ave., NW., Washington,
DC 20460-0001,

Subject: Metam-Sodium Revised Risk Assessments, Docket ID # OPP-2004-0159.

Metam-Sodium is a critically important soil fumigant in California. It is used across an extremely broad cross section of commodities to provide efficacious and affordable control of weeds, diseases and nematodes. Actually, the use of Metam-Sodium reduces the need to use herbicides and fungicides during the growing season. Furthermore, there are few alternatives to control soil organisms as our knowledge of the interactions in the soil is extremely limited. That said, Metam-Sodium has an extremely long track record as a reliable, versatile, cost effective soil fumigant that is essential to the agricultural community in California.

The continued ability to use this product to produce safe, affordable fruits, nuts and vegetables in California is now in jeopardy because of concerns relative to bystander exposure. It is appropriate and important to address these concerns and ensure that bystanders are not exposed to any harmful emissions and Western Growers supports the development of risk assessments that will allow for agriculture to develop and tailor practices that will mitigate any identified concerns. It is however highly critical that all scientific issues be adequately resolved during the development of the risk assessment and that any regulatory determinations be made only after careful consideration and direct involvement of the grower community. These determinations if made prematurely or hastily could significantly harm the California agricultural sector.

In that spirit Western Growers on behalf of our members, who grow, pack and ship approximately half of the United States fruits and vegetables, is pleased to have the opportunity to provide some comments on the current revised Metam-Sodium risk assessment.

General Comments

1. Western Growers supports the comments that have been developed and submitted by the registrants and we urge the USEPA to make the changes that have been suggested in those comments.
2. We firmly believe that all scientific issues that will impact the conclusions reached in the risk assessment and subsequently greatly influence the risk management decisions made in conjunction with the continued use and availability of Metam-Sodium must be adequately resolved. In this regard, we believe that EPA must provide adequate opportunity for and

consideration of all comments prior to the release of any subsequent draft. Several of the unresolved issues which must be appropriately finalized include:

- a. The agreement on an appropriate and acceptable model and modeling approaches that will be used to determine bystander exposure is paramount as it is the foundation of the risk assessment and will impact/affect all conclusions.
 - b. Registrants have not had access to key data that underlie some of EPA's most significant conclusions. All Metam-sodium stakeholders need access to these studies and related information to have an adequate opportunity to comment on the revised risk assessment documents but it is essential that registrants have the ability to review and correct any errors in assumptions or analysis in areas where they have direct data and expertise.
 - c. The open discussion and resolution of scientific issues is essential to a transparent process which is an EPA goal all compound in a re-registration eligibility decision (RED) development process. It is important that EPA adhere to the highest scientific standards in issuing assessments that have significant impact on agricultural operations. Western Growers is firmly convinced that, until such time as EPA has incorporated considerations of the Scientific Advisory Panel (SAP) and the data and assumptions within models have been reviewed and agreed upon by all, no further assessments should be released.
3. Western Growers believes that the California producers, pest control advisors and applicators are the most reliable and informed stakeholders with the greatest level of expertise on the use of Metam-Sodium. Their knowledge is essential to verifying any assumptions and or conclusions that are made based on use patterns including application methods, rates, timing, acres treated, etc. This is particularly important in the refinement of occupational (handler) exposure but will also result in better characterization of potential bystander exposure. The risk assessment must adequately survey these individuals and incorporate their feedback before any new assessment is released.

Specific Comments

4. In addition to the overarching issues listed above there are several key scientific errors within the current draft assessment that must be addressed.

These include:

- a. EPA's application of a 10x uncertainty factor to the human data is overly conservative.
- b. EPA should not apply an additional 10x intraspecies uncertainty factor to the no observed adverse effect level (NOAEL) of 220 parts per billion (ppb) determined in the human eye irritation study. There is no scientifically justified reason for the application of this safety factor.
- c. EPA should strongly consider the points made in the registrants' comments on the eye blink rate, which, as those comments discuss, is not consistent with prevailing science or conclusions of the California Department of Pesticide Regulation (DPR) assessment. DPR considered the nature of the effect (eye blink) and removed the 10x uncertainty factor. EPA should conclude similarly because DPR's conclusion on this point is scientifically supported and doing so would avoid inconsistent regulatory positions that are harmful to the grower community

- d. EPA should correct data discrepancies and use the corrected data in assessing risks from MITC. The data EPA used do not correspond well to the observed data on points key to EPA's risk assessment conclusions. The Metam-Sodium Alliance provided the corrected data in its comments on the preliminary risk assessment, and EPA should rely on those data.

Western Growers, like the registrants, are strongly committed to working with EPA to meet their obligations and deadlines with regard to Metam-Sodium. That said, Metam-Sodium is a critical product to many California growers and its relative importance and fit may increase as restrictions on other fumigants (such as the phase out of Methyl Bromide and the township caps associated with the use of Telone) increase. In this light it is critical that USEPA invest adequate time and resources on the further development and revision of this risk assessment such that it is an open process in which all stakeholders participate equally. Western Growers appreciates the opportunity to provide these comments and is committed to facilitating the involvement of the California production community. I will follow up soon to discuss and determine how the California production community may best serve in the further review and refinement of this assessment.

Sincerely

Hank Giclas
VP – Strategic Planning, Science and Technology